

# When Should Researchers Provide Clinical Care to Subjects?

Jaci Janka, M.D.  
NIAID, NIH

# The Research Question

- Little is known about the relationship in children between pulmonary hypertension and malaria infection.
- There is some evidence/reason to believe that....

# Study Value

- The hypothesis/goal of the study is...
- Evaluating the relationship between pulmonary hypertension and malaria infection in children could be important because..

# Population

- There are not a sufficient number of children with malaria to conduct the study in the U.S.
- Hence, NIH investigators propose to conduct the study in Africa, building on an existing collaborative relationship with researchers there.

# Communities

- The investigators plan to recruit N? children ages 1-14 who have severe malaria and healthy controls.
- Children will be recruited from a major pediatric malaria referral center as well as several villages.

# Study Procedures

- At baseline, children will undergo echocardiogram and blood testing to evaluate....
- The infected children will then undergo anti-malarial treatment and have repeat measures.

# The Question

- The investigators expect that their research tests will identify various conditions (e.g. sickle cell) and health needs in their subjects.
- They also expect to identify other conditions and health needs in the course of interacting with subjects.

# Insufficiency of Referral

- In some instances, the local health system may be able to handle the concerns identified.
- However, the investigators expect to identify numerous conditions that the local health system is unable to address.



# Consultation

- The investigators wonder to what extent they are obliged to provide medical care for these conditions.
- They call a bioethics consultation to discuss this question.